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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,262	07/18/2003	Arnaud Mainnemare	1254-03	4220

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IP GROUP OF DLA PIPER US LLP
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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,262

Applicant(s)

MAINNEMARE, ARNAUD

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a pharmaceutical composition comprising (i) at least one halogenated compound, and (ii) at least one N-halogenated derivative of at least one compound selected from zwitterionic and/or amino acid compound, wherein the composition does not generate substantial stimulation of myeloperoxidase activity in a mammal, classified in class 252/187.26; class 514, subclass 561.
- II. Claims 12-19, drawn to a method of preparing a pharmaceutical composition comprising mixing: (i) at least one halogenated compound, (ii) at least one N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, and (iii) optionally at least one pharmaceutically acceptable excipient, classified in class 252/187.26; class 514, subclass 561.
- III. Claim 20 and 22 drawn to a method for treatment and/or preventing viral infections, and/or bacterial infections, and/or parasitical infections, and/or fungal infections, and/or diseases generated from non conventional transmissible agents, in humans or animals and a method of modulating immunity in humans or animals comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical

composition comprising: at least one halogenated compound, and at least one N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, without substantial stimulation of myeloperoxidase activity in the human or animal, classified in class 252/187.26; class 514, subclass 561.

- IV. Claim 21, drawn to a method of treating chronic inflammation, and/or progressive inflammation, and/or acute inflammation in humans or animals comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical composition comprising at least one halogenated compound, and at least one N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, without substantial stimulation of myeloperoxidase activity in the human or animal, classified in class 252/187.26; class 514, subclass 561.
- V. Claim 23, drawn to a method of stimulating tissue healing in humans or animals comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical composition comprising at least one halogenated compound, and at least one N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, without substantial stimulation of myeloperoxidase activity in the human or animal, classified in class 252/187.26; class 514, subclass 561.

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- VI. Claims 24-26, drawn to a method of pre-surgically, and/or per-surgically, and /or post-surgically irrigating in humans or animals comprising contacting the surgical site with a composition comprising: at least one halogenated compound, and at least one N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, without substantial stimulation of myeloperoxidase activity in the human or animal, classified in class 252/187.26; class 514, subclass 561.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Groups III-VI are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product since the product can be use as an antiseptic.

Inventions Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be used to make another and materially different product as anti-microbial.

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Inventions Groups III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and effects because each of the medical disorder to be treated have different known treatment and have a different biological pathways involving different target cells.

Inventions Group II and Groups III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different operations because Group II is related to method of preparing or making a pharmaceutical composition while Groups III-VI are related to treatment of different medical conditions.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claims will not be rejoined. See MPEP 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with

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the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Sreenivasan Padmanabhan
Supervisory Primary Examiner
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Jmk

September 22, 2006